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\*Not admitted in New York

July 6, 2006

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Via Express Mail  
(EV 725787049 US)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

"Express Mail" mailing label No. EV 725787049 US	
Date of Deposit:	July 6, 2006
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Name:	Elie H. Gendloff
Signature:	

Re: U.S. Patent Application Serial No. 10/542,958  
(U.S. National Phase Entry of PCT/US04/01773)  
Title: USE OF MYCOBACTERIAL VACCINES IN CD4<sup>+</sup>  
OR CD8<sup>+</sup> LYMPHOCYTE-DEFICIENT MAMMALS  
Inventors: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov,  
Vasan Sambandamurthy and Sheldon Morris  
Our File: 96700/1031

Dear Sir:

Pursuant to our receipt of a "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)," enclosed please find the following documents for filing with the above-identified patent application in the names of William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov, Vasan Sambandamurthy and Sheldon Morris, entitled USE OF MYCOBACTERIAL VACCINES IN CD4<sup>+</sup> OR CD8<sup>+</sup> LYMPHOCYTE-DEFICIENT MAMMALS, comprising the following:

1. a copy of a "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" dated March 13, 2005 for the above-identified case (3 pages);
2. a "Reply to Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" with a two-month extension of time requested therein (4 pages);

July 6, 2006

3. a Fee Transmittal, Form PTO/SB/17 (1 page);
4. an executed Declaration in compliance with 37 C.F.R. § 1.497(a) and (b) (5 pages total);
5. a "Declaration for Utility Patent Application Under 37 C.F.R. 1.63" executed by deceased inventor Stoyan Bardarov's legal heir (2 pages);
6. a Sequence Listing in both computer-readable form (1 diskette) and written form (10 pages);
7. an Information Disclosure Statement, Forms PTO/SB/08A (1 page) and PTO/SB/08B (4 pages) with 33 non-US patent references attached thereto;
8. an Amster Rothstein & Ebenstein LLP check in the amount of \$290 to cover the two-month extension of time fee and the late declaration surcharge, claiming small entity status; and
9. a return receipt postcard.

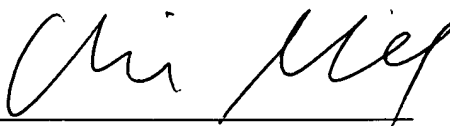
Small entity status was previously established and is still proper.

Please acknowledge receipt of the enclosed papers by stamping the enclosed postcard and returning same to us.

Respectfully submitted,

Amster, Rothstein & Ebenstein LLP  
Attorneys for Applicants  
90 Park Avenue  
New York, NY 10016  
212 336 8000

Dated: New York, New York  
July 6, 2006

By:   
Elie H. Gendloff  
Registration No. 44,704

07/13/2006 GFREY1 00000122 10542958

01-FC:2617  
02-FC:2252

65.00 OP  
225.00 OP

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2006**☒ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$)**290****Complete if Known**

Application Number	10/542,958
Filing Date	January 23, 2004 (I.A.)
First Named Inventor	William R. Jacobs, Jr.
Examiner Name	to be determined
Art Unit	to be determined
Attorney Docket No.	96700/1031

**METHOD OF PAYMENT** (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 01-1785 Deposit Account Name: AMSTER ROTHSTEIN & EBENSTEIN LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION** (All the fees below are due upon filing or may be subject to a surcharge.)**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 20 or HP = _____ x _____ = _____		
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 3 or HP = _____ x _____ = _____		
HP = highest number of independent claims paid for, if greater than 3.		

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).


<b>Total Sheets</b>	<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
_____ - 100 = _____	_____ / 50 = _____	(round up to a whole number) x _____	= _____	

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): late declaration surcharge and two-month ext. of time fee - small entity status

**Fees Paid (\$)****\$290****SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	44,704	Telephone	212-336-8000
Name (Print/Type)	Elie H. Gendloff	Date	July 6, 2006		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/542,958	William R Jacobs JR.	96700/1031

INTERNATIONAL APPLICATION NO.
-------------------------------

PCT/US04/01773

I.A. FILING DATE	PRIORITY DATE
01/23/2004	01/24/2003

1912

AMSTER, ROTHSTEIN & EBENSTEIN LLP  
 90 PARK AVENUE  
 NEW YORK, NY 10016

CONFIRMATION NO. 2060

371 FORMALITIES LETTER



\*OC000000018230036\*

Date Mailed: 03/13/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 07/21/2005
- Copy of the International Search Report filed on 11/14/2005
- Copy of IPE Report filed on 11/14/2005
- Preliminary Amendments filed on 07/21/2005
- U.S. Basic National Fees filed on 07/21/2005
- Priority Documents filed on 07/21/2005
- Specification filed on 07/21/2005
- Claims filed on 07/21/2005
- Abstracts filed on 07/21/2005
- Drawings filed on 07/21/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$65 for a Small Entity:

- **\$65 Surcharge.**
- This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c) Applicant must provide an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application** and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/542,958	PCT/US04/01773	96700/1031

FORM PCT/DO/EO/905 (371 Formalities Notice)

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

Application No. : 10/542,958 Confirmation No. 2060

Applicant : William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov,  
: Vasam Sambandamurthy and Sheldon Morris

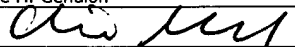
Filed : January 23, 2004 (I.A.)

TC/A.U. : Not determined

Examiner : Not determined

Docket No. : 96700/1031

Customer No. : 1912

"Express Mail" mailing label No.	EV 725787049 US
Date of Deposit:	July 6, 2006
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Name:	Elie H. Gendloff
Signature:	

REPLY TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE  
UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Reply is to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) dated March 13, 2006 in the above-identified application. Applicants hereby request a two-month extension of time for filing this Reply, and include with the enclosed check the small entity fee of \$225 to cover the two-month extension of time. With that extension, this Reply is due July 13, 2006 and is timely filed.

Oath or Declaration

Enclosed herewith is a Declaration of the inventors, executed by Inventors Jacobs, Hsu, Sambandamurthy, and Morris, for the above-identified patent application believed to be in compliance with 37 C.F.R. 1.497(a) and (b). Also included is a Declaration for

Utility Patent Application Under 37 C.F.R. 1.63 for deceased inventor Stoyan Bardarov, executed by inventor Bardarov's heir, Svetoslav Bardarov.

Sequence Requirements

Enclosed herewith a sequence listing in both paper and computer-readable forms for the above-identified patent application, previously filed in the international stage of this application, PCT/US04/01773. The content of the sequence listing information recorded in computer readable form is identical to the written (on paper) sequence listing. This sequence listing includes no new matter.

Information Disclosure Statement

Enclosed herewith are Forms PTO/SB/08A (1 page) and PTO/SB/08B (4 pages) and copies of the 33 non-US patent references listed on Forms PTO/SB/08A and PTO/SB/08B.

Amendment

Please enter the following amendment to the instant patent application.

Specification Amendment

Please enter the enclosed sequence listing into this patent application.

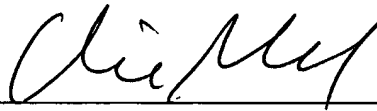
Remarks

It is believed that the enclosed \$290.00, covering the late Oath or Declaration surcharge and a two month extension of time (small entity), is all that is required with this Reply. However, if there are unanticipated fees required to maintain pendency of this application, the USPTO is authorized to withdraw the payment for those fees from Deposit Account 01-1785.

Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP  
Attorneys for Applicant  
90 Park Avenue  
New York, NY 10016  
(212) 336-8000

Dated: New York, New York  
July 6, 2006

By:   
Elie H. Gendloff  
Registration No.: 44,704